

## Original Article

# FEASIBILITY OF USE OF COVERED STENTS IN COARCTATION OF THE AORTA AND ITS IMMEDIATE OUTCOME

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# Author's Contribution

AB:Conducted the study and wrote the article. MS:Helped in review the article. AUR:Re-arranged data and corrected article. MY:Tables and figures. TA made corrections and did the proof reading.

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#### **ABSTRACT**

BACKGROUND: Endovascular stenting in coarctation of the aorta is preferable in adolescents and adults, as it is carries less risk of restenosis and aneurysm formation. There is limited study data for early results of using covered stents, as primary treatment in a developing country. In our setup repeat intervention and follow up are main challenges.

OBJECTIVE: To see the feasibility of use of covered stents in coarctation of aorta and its immediate outcome.

MATERIAL AND METHODS: This was a case series of patients with coractation of aorta. A total of 22 patients were included regardless of gender with age about 18 years. Twenty two patients were implanted 23 covered stents (Cheatham-Platinum stents) at a single center, CPE Institute of Cardiology, Multan, Pakistan. One patient had emergency rescue treatment. Mean age was 20 +8 (range 11 to 39) years and mean weight 48.6 +7 (39 – 60) kg. Variables measured were regression of peak to peak systolic gradient and an increase in diameter of coarctation site narrow point.

RESULTS: 22 patients underwent implantation of Covered Cheatham Platinum (CP) stents from February 2010 to June 2019. There was significant reduction of mean systolic gradient from 42 + 2 mmHg to 8 + 6 mm Hg (P< 0.0001). There was significant increase of mean diameter of coarctation narrow point from 3.9 mm (+0.2) to 14.9 mm (+1.7 mm). There was no death. No patient developed dissection or aneurysm formation when evaluated 24 hrs after the procedure. No patient had a stent migration or stent fracture. No case was abandoned or referred for surgery. Three patients had blood transfusion during the procedure due to bleeding while procedure. External iliac artery injury requiring immediate stenting was needed in one patient. Two patients had loss of lower limb pulses which was resolved successfully with anticoagulation by using heparin infusion. One patient had thrombus formation at right brachial artery requiring embolectomy by forgarty catheter with no residual loss.

CONCLUSION: Covered Cheatham Platinum stents are safe and effective in the management of coarctation of the aorta in adolescents and adults. It is a feasible option in a resource-limited country where re-intervention and follow up are major issues. Long term result show ever, need to be in follow-up study.

KEYWORDS: Congenital heart disease, Coarctation of the aorta, stent implantation

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#### INTRODUCTION

oarctation of the aorta is 5-8% of congenital heart diseases. It may be an isolated lesion. Other cardiovascular association are bicuspid aortic valve, hypoplastic aortic arch, mitral valve abnormalities, ventricular septal defect and patent ductus arteriosus (PDA).<sup>1, 2</sup> 10% patients have cerebral aneurysm. <sup>3, 4</sup>

In our part of the world, coarctation of the aorta is not uncommonly missed and first presentation is in adolescence or adult age group classically with upper limb hypertension. Untreated long-term sequela from untreated coarctation of the aorta include congestive heart failure, endocarditis, aortic rupture or cerebrovascular hemorrhage.<sup>5</sup> Transthoracic echo is primary imaging tool and CT angiogram is a useful noninvasive modality, which helps in planning the best mode of treatment.<sup>6</sup>

Neonates, infants and young children are treated by surgery.  $^{7-10}$  Treatment is indicated when there is blood pressure difference of >20 mmHg between arms and legs. In adults, upper limb hypertension (>140/90 mmHg in adults) and abnormal response of blood pressure to exercise are class I indication for intervention.  $^{11, 12}$  Balloon angioplasty may be done after the age of 6 months. But the risk of dissection and / or aneurysm formation is higher. Endovascular sent implantation is preferable over balloon angioplasty in children (> 25 kg) and adults, as it has less chances of aneurysm formation.  $^{13, 14}$ 

#### MATERIALS AND METHODS:

This retrospective descriptive case series was carried at CPE Institute of Cardiology, a tertiary care hospital in Multan, Pakistan from Feb 2010 to June 2019. Convenience sampling was done to include patients who had coarctation of aorta involving thoracic descending aorta with more than 20 mmHg gradient. Minimum weight criteria was more than 25kg while age was more than 18 years. Patients with angiography evidence of arteritis were excluded. One patient who had transverse arch coarctation was also excluded. Success of the procedure and complications were described. Variables measured were regression of peak to peak systolic gradient and an increase in coarctation site narrow point. Approval was taken from the institutional ethical committee. Patients or the family awarded the consent. Diagnostic catheterization was performed to delineate morphology and record pressures. However the procedure was performed at a later time under general anesthesia after arranging disposables. Femoral artery and

vein access were taken. Heparin was administrated at 100 Units /kg to keep activated clotting time above 220 seconds. Angiograms are done in left lateral view or shallow left ant oblique view (LAO) to delineate the anatomy. The measurements were done for narrow point, transverse arch, isthmusand descending aorta at the level of the diaphragm.

Appropriate lengths of stent and balloon were selected. CP stent (NuMed Inc., Hopkinton, New York) was used in all our cases. Its advantage is higher radial strength so it was preferred in adult patients.

#### PROCEDURE:

A long Mullen's sheath (Cook Inc., Bloomington, IN) was passed over the extra stiff wire parked in ascending aorta. The stent is tightly crimped manually over the selected balloon so that stent did not slip of the sheath while being inserted through the diaphragm of the sheath. Angiography was done to check for the position of stent before balloon inflation. The assembly of stent and balloon was taken through the long sheath. After positioning was confirmed, long sheath is withdrawn while keeping stent-balloon assembly in place in order to expand the stent. RV pacing was done at a rate to reduce systolic pressure to less than 50 mmHg during balloon inflation. Firstly, inflation of the inner balloon was done followed inflation of by outer balloon. The balloons were deflated in the same sequence. Pacing was stopped at this moment. Check angiograms are done to ensure appropriate positioning of the stent. The balloon was removed and pull back gradient measured across the coarctation. Stent implantation is considered successful if pressure gradients decrease to less than 20mmHg across the coarctation site and improvement in the coarctation site narrow point diameter > 80% of the adjacent aortic arch diameter. 13, 15 If needed, further balloon dilatation is decided after gradients have been recorded. Blood pressure monitoring is done after procedure for paradoxical hypertension. Echocardiography is done before discharge for residual gradients, LV functions and detection of any other complications. Aspirin (5 mg/kg) is continued for 6 months after discharge. CT aortogram is performed in selected patients before the procedure to delineate the morphology and plan intervention.

#### **RESULTS:**

A total of 22 patients underwent stenting for native coarctation of the aorta (Table 1). Mean age was 20 + 8 (range 11 to 39) years and mean weight 48.6 + 7 (39 – 60) kg. They were



TABLE 1: Indications and no.

Severe CoA	22
Atresia	Nil
Left subclavian artery close to coarctation site	3
Tortuous aortic arch	2
Dissection	1
Transverse arch coarctation	Nil
Age above 40 years	Nil
Associated PDA	Nil
Long segment coarctation	1
Turner Syndrome	Nil
Bare metal stent related complications	Nil
Stent fracture exercise, or significant LV hypertrophy (class I, level C)	Nil

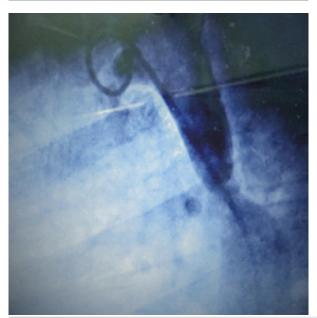
Table 2: Complications and numbers

F	A (manage at anti-male at ation)	
Femoral artery disruption	1 (rescue stent implantation)	
Femoral artery thrombosis	2 (treated with IV heparin infusion)	
Thrombus at left brachial artery	1 (successful embolectomy)	
Bleeding requiring transfusion	3	
Stent migration	Nil	
Aneurysms	Nil	
Dissections	Nil	
Pseudo-aneurysms	Nil	
Intramural hematoma	Nil	
Aortic wall rupture	Nil	
Paradoxical hypertension	Nil	

diagnosed on the basis of transthoracic echocardiagraphy primarily.

Covered Cheatham Platinum (CP) stents (NuMED, Hopkinton, NY) were implanted in 22 patients while one patient received an additional covered stent as rescue. Lengths used for CP stents were 34 mm (n=7), 39 mm (n=12) and 45 mm(n=3). BIB balloon was used in 19 patients (7x14 n=4, 8x16 n=9, 9x18 n=6) (Figure 1). Double balloon technique was used in three patients in whom the left subclavian artery was close to the coarctation site (two 10x4 Osypka VACS II balloons over two 0.035" wires, one parked in ascending aorta and other in left subclavian artery), (Figure 2).

There was significant reduction in gradient from ascending to descending aorta in all our patients, from  $42 \neg \neg \neg \neg + 2$  mmHg to 5 + 6 mmHg ( $2 \le 0.0001$ ). ). Mean narrow point diameter increased from 3.9 mm (+0.2) to 14.9 mm (+ 1.7 mm). There was no death during or immediately after the procedure. One patient had external iliac artery



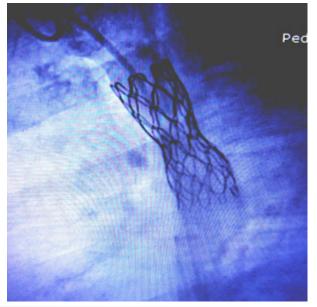


Figure 1: Aortograms showing coarctation of Aorta (before and after stent implantation)

injury requiring immediate rescue stenting (Table 2). Two patients had loss of lower limb pulse. This issue resolved successfully with heparin infusion. One patient had thrombo-embolism in right brachial requiring embolectomy by forgarty catheter with no residual effects. No patient developed dissection or aneurysm immediately after the procedure. One patient had preexisting aneurysm, which closed after stenting. No patient had stent

migration or fractures. No case was abandoned or referred for surgery. Three patients had blood transfusion, (one pint each) during the procedure. Echocardiography performed before discharge showed that all patients had a good result with no significant gradient across the coarctation site and adequate LV function. None had pericardial effusion or any other complication detected on echocardiography.

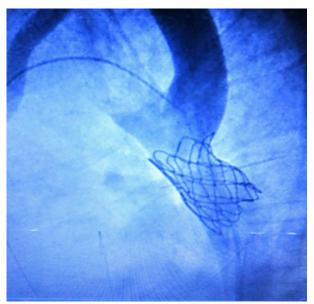


Figure 2: Aortogram: Double balloon technique preserved flow to the left subclavian artery

#### **DISCUSSION:**

Treatment of coarctation of the aorta in adolescents and adults is challenging. The use of covered stent is increasing and has a special role in developing countries like Pakistan where repeat procedure and follow up is a challenge. Limited variety of covered stent is available in Pakistan and we used covered Cheatham-Platinum stent for all of our patients. <sup>15</sup>

There is limited data available from developing countries with the use of covered stents as definitive treatment in Coarctation of the aorta. Sadiq et al. 16 reported data of 59 patients who received covered Cheatham-Platinum stents with similar results. One death was reported due to cerebral anoxia related to anesthesia. One patient developed dissection post-procedure. This study also evaluated follow-up after 45.9+3.9 (3-120) months. Computed tomography showed no migration or fracture. Re-dilatation was done successfully in four (7.1%) patients. 37 (66%) patients' had their anti-hypertensive medicine decreased or stopped.

COAST II trial <sup>17</sup> is a multi-center study reported data of 158 patients with success rate was 92%. There was no acute wall injury, repeat intervention or death.

Our study did not include follow up of the patients, which is major limitation of the study. This is crucial with reference to late complication such as aneurysm formation or re-coarctation. Follow-up

CT angiography should be done 6 and 12 months after the stening. It should be repeated at intervals of 5 years or less, with case-to-case variation. Chronic hypertension remains present in 35-68% of the patients with CoA, despite anatomically satisfactory repair. 18-20

One major difficulty with covered CP stent is use of large size sheath, which increased the risk of bleeding and trauma to the artery. One of our patients developed hypotension and fortunately survived with no residual sequel after rescue treatment done by putting a second covered stent at site of injury at external iliac artery. One way to tackle this issue is to do serial dilatation. Bruckeimer used smaller sheaths and did further dilatation on average 5 months post initial procedure in 9/22 patients. <sup>21</sup> This however, adds significant cost and is not practical in our set-up.

Occlusion of left subclavian artery and spinal artery is a concern whilst using covered stents in Coarctation of the aorta. Left subclavian artery may be covered without any consequences 16, but there are reports in the literature where left arm claudication needed extra-anatomic bypass to alleviate symptoms. <sup>22</sup> Double balloon technique used in with one wire parked in left subclavian artery and other one parked in ascending aorta. We used this technique in 3 of our patients to prevent jailing of left subclavian artery. Spinal artery arises below the 9th thoracic vertebrae and no case has been reported yet in which stent has led to spinal artery injury.

The risk of aortic rupture was not eliminated <sup>15, 22</sup>. Aortic rupture is reported by Kenny et al. in 2/37 patients with coarctation of the aorta. <sup>23</sup> One patient needed emergency surgery due to leak from the proximal aspect of the stent. Trauma by the long sheath is also reported in one patient. Rupture caused by the second balloon dilation is also reported in case when distal part was under deployed. <sup>24</sup> None of our patient developed dissection or rupture following covered stent implantation.

### CONCLUSION

Covered CP stent is safe and effective treatment when carefully selected patients with severe coarctation of the aorta in adolescents and adults. This is crucial in resource limited countries where cost of a repeat procedure and follow up are major concerns. Systemic hypertension, re-coarctation and repeat interventions must be evaluated by long-term follow up study.



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